UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SYMED LABS LIMITED, et al., Plaintiffs, vs. ROXANE LABORATORIES, INC., Defendant.	.	Case No. 15-cv-08304 Newark, New Jersey December 16, 2016
SYMED LABS LIMITED, et al., Plaintiffs, vs. AMNEAL PHARMACEUTICALS LLC, Defendant.	.	Case No. 15-cv-08307
SYMED LABS LIMITED, et al., Plaintiffs, vs. GLENMARK PHARMACEUTICALS INC., USA, Defendant.	.	Case No. 15-cv-08306

TRANSCRIPT OF HEARING
BEFORE THE HONORABLE MARK FALK
UNITED STATES MAGISTRATE JUDGE

Audio Operator:
Transcription Service: KING TRANSCRIPTION SERVICES
3 South Corporate Drive, Suite 203
Riverdale, NJ 07457
(973) 237-6080

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(APPEARANCES continued)

For the Plaintiffs:	CHRISTINA LYNN SAVERIANO, ESQ. Hill Wallack, LLP 21 Roszel Road Princeton, NJ 08543 (609) 734-6395 csaveriano@hillwallack.com
	MARK S. GRAHAM, ESQ. The Graham Law Firm PLLC 507 South Gay Street, Suite 1230, Knoxville, TN 37902 (865) 633-0331
For the Defendant Roxane Laboratories, Inc.:	BETH S. ROSE, ESQ. Sills Cummis & Gross P.C. One Riverfront Plaza Newark, NJ 07102-5400 (973) 643-7000 brose@sillscummis.com
	EMILY C. MELVIN, ESQ. Latham & Watkins 330 North Wabash Avenue, Suite 2800 Chicago, IL 60611 (312) 876-7645 Emily.melvin@lw.com
For the Defendant Amneal Pharmaceuticals LLC:	ANANDITA VYAKARNAM, ESQ. Budd Larner PC 150 John F. Kennedy Parkway Short Hills, NJ 07078 (973) 315-4421 avyakarnam@buddlarner.com
For the Defendant Glenmark Pharmaceuticals Inc., USA:	JAMES S. RICHTER, ESQ. Winston & Strawn, LLP The Legal Center One Riverfront Plaza 7th Floor Newark, NJ 07102 (973) 848-7676 Jrichter@winston.com

(APPEARANCES continued)

IVAN M. POULLAOS, ESQ.
Winston & Strawn LLP
35 W. Wacker Drive
Chicago, IL 60601-9703
(312) 558-7962

(Commencement of proceedings at 12:15 P.M.)

THE COURT: Okay. This is Symed Labs and Hetero USA -- and Hetero USA versus Roxanne, 15-8304; Symed Labs and Hetero versus Glenmark, 15-8306; and Symed Labs and Hetero versus Amneal, 15-8307.

I wonder if counsel could put their appearances on the record, please.

MS. SAVERIANO: Good morning, Your Honor, Christy Saveriano from Hill Wallack on behalf of the plaintiffs.

THE COURT: Oh, yeah.

MR. GRAHAM: Mark Graham, the Graham Law Firm on behalf of plaintiffs.

THE COURT: Okay.

MR. RICHTER: Good morning, Your Honor, James Richter of Winston & Strawn on behalf of Glenmark Pharmaceuticals.

And with me today is Ivan Poullaos also from Winston & Strawn.

MS. MELVIN: Good morning, Your Honor, Emily Melvin from Latham & Watkins on behalf of Roxane.

THE COURT: Okay.

MS. VYAKARNAM: Good morning, Your Honor, Anandita Vyakarnam from Budd Larner for Amneal Pharmaceuticals.

MS. ROSE: Good morning, Your Honor, Beth Rose from

Sills Cummis on behalf of Roxane.

THE COURT: Okay. Thank you.

We have a number of things to deal with this morning. And I received a lot of correspondence. And I thought it's time to do this officially on the record. And I want to repeat the history of what has occurred here and then get to the issues.

So I'm going to start with that, and then of course I'll hear from you.

But the last conference that we had was held on October 26th. And since that date, I've received, I think, seven letters, the most recent being about 5:30 or so yesterday afternoon, something like that.

Basically, this is a patent infringement case. Plaintiffs are the owners by assignment of four patents covering a product with line Linezolid -- I don't know how to pronounce that, so you can help me with that. But the product Zyvox; it's an antibiotic. The cases are consolidated for discovery.

Fact discovery presently closes on July 24th, 2017. And I guess pursuant to the operative scheduling order, which is the fifth amended scheduling order, the parties are currently exchanging proposed claim constructions and supporting evidence.

As I said, the last conference was October 26th. I

hadn't heard anything or any problems with the case or anything for some time before that. The day before the conference, I got a letter from defendant Roxane, really on behalf of all defendants, raising a dispute over the terms of a proposed discovery confidentiality order. The issue had been raised in August 2016, but I didn't hear anything from the parties, and the parties did nothing about it, to my knowledge, until October 25th, the day before the conference.

Defendants wanted the order to include certain provisions relating to the access to confidential information and highly confidential information; not an uncommon dispute in these types of cases.

I directed the parties to -- the plaintiffs to respond to the October 25th submission by November 9th.

No timely response was submitted, but eventually on November 22nd, plaintiffs requested until November 29th to respond. For some reason, it wasn't neither granted nor denied, and there was reference to it in some of the papers filed by the defendants as being waived and things like that, but ultimately plaintiffs did put in a responsive letter on November 30th. And defendants contend I shouldn't even consider the letter because it was late. And I'm certainly going to use my discretion to consider it, notwithstanding the fact it was late, and also because we need the issues decided on the merits here in this important patent case.

So that the parties can't agree on a DCO. Both parties seem to agree that the DCO should have two tiers of protected information: confidential and highly confidential information.

However, the defendants have apparently requested the entry of a discovery confidentiality order that has three extra provisions. The defendants want to preclude any nonattorneys from seeing any protected information, confidential and highly confidential, exchanged in the case. I mean -- which is a very broad request, although it does occur in certain patent cases.

Defendants want in-counsel's [*sic*] access limited to confidential information -- in-house counsel's, meaning that they can't review highly confidential information.

And, three, if we permit, if the Court permits in-house counsel access to highly confidential information, defendants want an in-house -- the in-house counsel to be permanently barred from competitive decision-making related to the technology and products underlying the patents.

Now, plaintiff's responsive letter states that it should be entitled to a discovery confidentiality order that allows disclosure of all highly confidential material to at least two individuals, who are identified as John Thallemer, Esquire, in-house U.S. patent counsel, and Mr. Suresh Reddy, who is Symed's Indian-based patent agent.

So the dispute raises a question of access that has been discussed in some case law, that's referred to somewhat fleetingly in the letters, a Federal Circuit case, United States Steel v. U.S., 730 F.2d 1465, and *In re* Deutsche Bank Trust, 605 F.3d 1373. U.S. Steel involved access to confidential documents under a protective order. *In re* Deutsche Bank discussed both the question of access and also the -- specifically the patent prosecution bar. And the general principles, I'm going to review, because I think it goes to what we do here.

But with respect to access to confidential and highly confidential information, the party seeking the protective order carries the burden of showing good cause for its issuance. And the same is true for a party seeking to include access provisions in a DCO. That's Deutsche Bank at page 1378.

Now, counsel can't be denied to access to confidential information solely on the grounds that they hold the general position of in-house counsel. That's also Deutsche Bank and U.S. Steel at page 1378; U.S. Steel at 1467. The question of access turns on whether there is an opportunity for inadvertent disclosure, which must be determined by the facts on a counsel-by-counsel basis. *In re* Deutsche Bank at 1378; U.S. Steel at 1467. The counsel-by-counsel determination should turn on the extent to

which counsel is involved in competitive decision-making with the client. *In re* Deutsche Bank, the same pages, and U.S. Steel.

Competitive decision-making is, quote, a shorthand for a counsel's activities, association, and relationship with a client that are such as to involve counsel's advice and participation in any or all of the client's decisions, (pricing, product design, things like that), made in light of similar or corresponding information about a competitor.

So that's really with regard to access. There's a lot of law -- I'm not going to read through all of it -- when it comes to a patent prosecution bar that some of it's the same thing. And basically, they say, for example, in Deutsche Bank says it's very important for the court in assessing the propriety of the exemption for patent prosecution bar and also I think this applies to the access as well, to examine all of the relevant facts surrounding the counsel's actual preparation and prosecution activities on a counsel-by-counsel basis.

And, I mean, it goes on and on, and really, I think you're familiar with the cases that -- let me just see here. And I think it's -- the case that I think is somewhat helpful is a case called Front Row Technologies LLC v. NBA Media Ventures, 125 F. Supp. 3rd 1260. I'm going to quote from it: The majority of courts first require the movant to show that

there's an unacceptable risk of inadvertent disclosure of confidential information determined by the extent to which counsel is involved in competitive decision-making with its client. The movant must demonstrate this risk on a counsel-by-counsel basis. Second, the movant must show that the proposed prosecution bar is reasonable in scope. And then only after these steps are complete, does the burden shift to the nonmovant. The party seeking an exception to bar must show that counsel's representation of the client in matters before the PTO does not and is not likely to implicate competitive decision-making related to the subject matter of the litigation so as to give rise to inadvertent use of confidential information. And also to consider the potential injury to the moving party from restrictions imposed on its choice of litigation and prosecution counsel outweighs the potential for injury to the opposing party caused by such inadvertent use.

So that's sort of a general statement of the legal standards of access and also patent prosecution bars.

So then we come to the issue before us, the analysis. And frankly, I struggled with it based on the papers that were submitted. I mean, I'll note right at the outset that there were no affidavits submitted. And I don't know anywhere, there's a lot of cases that I can cite to you where they rely on affidavits, more detailed affidavits

rather than just general conclusions. I don't know that's -- you know, that's not a requirement in the law, but, you know -- so when we get to the question of access, like I said, it's a case-by-case, attorney-by-attorney inquiry. I mean, I think that the defendants have, you know, certainly established the basic issue here that we're dealing with highly confidential material and things like that.

So, you know, I think that they argue -- the defendants argue there's a high likelihood of economic injury because the parties are direct competitors for the sale of the generic product, and they claim that -- defendants claim plaintiffs want to disclose the information to individuals who are involved in technical development of the active pharmaceutical ingredient in the case, the API.

Specifically, defendant alleges plaintiffs have a pending patent application involving the product in the United States, which involves the same inventors as the Patent-in-Suit. And since everyone's competing in the market, as well as the pending application, they claim the risk of injury is high and that the potential for misuse is too great.

And they also claim that it's disclosure of the highly confidential information to in-house counsel is unnecessary and should be prohibited, you know, based on the risk of inadvertent disclosure. And defendants argue that

plaintiffs have essentially admitted that their in-house counsel intends to engage in the use of information for the development of products, you know, to compete with the same API. So the argument there is defendants contend that intentional or not, in-house counsel will not be able to separate or wall off in their mind highly confidential information reviewed in the case and that plaintiffs should be able to proceed with the case with only outside counsel and experts reviewing.

Now, plaintiff -- then we come to the plaintiff's response, and it's problematic to me. But the plaintiff's response doesn't focus on the specific terms that should or should not be included in the DCO. The letter simply states in a conclusory fashion that it should be entitled to a DCO that allows disclosure of all confidential material to at least two individuals, John Thallemer, who is in-house U.S. patent counsel, and Mr. Suresh Reddy. And plaintiffs state -- and they do so conclusory, in a certain way, that these individuals are not involved in competitive decision-making.

But the letter submitted, which, once again, was a letter, not an affidavit, which I think would be more appropriate in something like this, is devoid of any specifics, any substance about the activities of these two individuals. It just says what they are and that they're

not, you know, involved in competitive decision-making.

Well, you know, I think that it's a case where a access -- I think the defendants have established that access -- it would be appropriate to limit access in this case. However, I'm not willing to have this broad access, at least not at this point, restriction that seems to be asked for at the outset, to anyone. Anyone who's not a lawyer -- you know.

So I'm going to -- you know, I'm going to give you another chance, actually, plaintiffs. The Court's required to evaluate on a counsel-by-counsel basis, the risk of inadvertent disclosure, which turns on whether -- I've already said this -- the individuals involved are competitive decision-makers.

I got a few sentences in the letter saying they're not. And there's, you know -- there's no information there. There's no meat on the bones. There's no details. Who are these people? What are their jobs? What do they do? Have they ever engaged in this, that, and the other thing? And I think that, really, you need to show that. I mean, at this point, I'm going to -- you know, things will remain restricted, but I'm not inclined to have a complete restriction. But I need some details. And I don't have the details. I'll cite the case of Sanofi-Aventis v. Breckenridge, which a New Jersey case, 2016 WL 308795, where

the court, they talk about reviewing affidavits from the individuals seeking access, you know, being specific about what they do and what they don't do and why they're not involved in competitive decision-making.

And here, we just got a couple of conclusory statements.

So I don't know how -- if you want to respond, Plaintiff, you know, I need many of details to decide it the right way. And they're not here.

So I don't know if anyone has anything to say, I'm happy to hear from you.

MR. GRAHAM: Your Honor, if I could respond to that one point, and I appreciate Your Honor's careful analysis of this issue, because it is very important --

THE COURT: Yes, it is.

MR. GRAHAM: -- to the plaintiffs. The -- in the -- or with the letter we submitted yesterday, we did include some flesh on the bones with regard to Mr. Thallemer. Your Honor may -- the Court may have not have had an opportunity to study that at this point. But we did have a sense that there may not be enough detail with regard to these individuals. We did offer that to some extent in a declaration filed by Mr. Thallemer yesterday.

THE COURT: Oh, I didn't see it. I'm sorry. But I wasn't here yesterday. Yesterday was the Court's holiday

party and judges meeting. So I mean, I didn't get a chance to see that.

MR. GRAHAM: I can appreciate that. But we will certainly take that very seriously and we'll submit appropriate details to allow the Court to make a more informed decision about this issue with regard to both individuals.

THE COURT: Yeah, I mean, I think we should do it quickly. I mean, the tone of the letters is that you want me to sort of move this along, and I'm happy to do it. But, you know, rather than just -- you know, I want to make the decision with more facts. And then I'll make the call as to that.

And then I can address the patent prosecution thing, if we get to that point. So, yes, counsel.

MS. MELVIN: If I may, Your Honor, I do have a copy of the declaration, if Your Honor would like it. The declaration actually related to a separate issue which was the disclosure of information to Mr. Thallemer. And I actually don't believe that the majority of the declaration discusses his competitive decision-making. In fact, there's only one sentence which says I am not involved in the prosecution of any patent applications or any upper-level competitive decision making with either of the plaintiffs in this case.

THE COURT: So, well, I mean let's talk about that. So let's say that's -- I mean, I think the way to dress that up is to say what they -- what the person does do and that -- whatever. But are the defendants, do you know these people? Or you're vigorously opposed to having these two individuals, knowing that I'm not likely to restrict completely -- a complete restriction. I don't think it's necessary. I'm very, very reluctant to do it, although I will note that there are cases where it is done, as you know.

But what about that? So what -- do you have information about these two individuals?

MS. MELVIN: We don't have much, Your Honor. You know, all we have is the same information that Your Honor has, which is that they state that they are not involved in competitive decision-making.

We note that with respect to Mr. Reddy, my understanding is Mr. Reddy is actually a patent agent, not an attorney. My understanding of patent agents is that they are typically involved in exactly the prosecution of patents that we're concerned about, but we don't have more details than that, Your Honor. And I think that is one of the biggest problems.

Additionally, we had this other provision -- you know, as Your Honor noticed -- noted, this analysis has to be done on a counsel-by-counsel basis. And plaintiffs have also

requested that confidential information be given to any officer, director, or other person or agent in play or agent reasonably necessary for the case.

We have asked who they had in mind so that we could further evaluate that. But we've gotten no further details. And we're very concerned about allowing such broad access when we don't know specifically to whom that information is going. It very well could be going to their technical people who are involved in the development of their products. It could be going to their patent prosecution -- individuals who are involved in their patent prosecution. And greatly concerning to us, because, of course, those individuals, once they have the information, they can't unlearn it.

THE COURT: Well, it's true. But I mean, what you say -- I mean, you know -- I don't know about Reddy, but, you know, when you get to -- you know -- well, we've got to see who's going to have access to the information. But at that point, you know, I think that defendant has a burden to show, you know, when we talk about patent prosecution bars that might also be imposed, a temporal restriction would be reasonable under Deutsche Bank. And in the papers, it seemed to me that plaintiff seemed to be willing to accept 18 months. Forever is not reasonable. And I wonder -- I was thinking somewhere along the lines of two years, when we get to that. Not really there yet.

But I hear what you're saying. I think we need a little more detailed information.

And as to -- sharing it with all the directors and officers, I don't know. I mean, you know, I didn't see that really fleshed out. But -- because I thought that plaintiff was saying in the letter -- Mr. Graham, you can correct it if it's not true, that you were -- only wanted -- or you're only really insisting on restricting access for two people.

Is that correct? That's what it seems to say in your letter.

MR. GRAHAM: Yes, sir, that's our -- I think where we are --

THE COURT: Okay.

MR. GRAHAM: -- conceptually with this matter right now. But there is a lack of definition at this point as to the terms, and so I agree that we need to have a specific document we are working with that has specific language with specific names on it. And absolutely, we are -- would like to be able to satisfy the Court's need for details with regard to these individuals.

I would ask if we could know, since, I obviously had some confusion, after our last meeting, about dates and so forth, when we -- if we could maybe get a briefing schedule that would be put at -- put in place or something --

THE COURT: I'll put it in an order, sure. But

you -- you make up the briefing schedule. You -- counsel. And if you can't agree, then I will.

But those kinds of things I'm going to give you -- I mean, you know, we have to move the case along at that it's been around a while with these '15 docket numbers, for lots of reasons. There's no real criticism, although there were some periods where I don't know what was going on.

But that said, I would -- come up with a schedule for that. That's what -- you know, I have no problem with that. You do that right there.

That's part of the issue. I mean, I need to get a working document here. For example, the defendants are talking in their letters about terms. And plaintiff is talking about two people. And we've got to sort of get on the same page. We've got to -- I'd like to see what we're talking about. So, you know ... I don't know. I guess you also seem to have a scheduling dispute, but I think that may be resolved at this point. The letters were from early December. Right?

Yes, what's the story with that?

MR. GRAHAM: On the schedule -- did you want to talk --

THE COURT: We're talking different schedules here, yeah. I mean.

MR. GRAHAM: Different schedules.

THE COURT: No, as to this issue, I'm going to give the plaintiff a chance, but I'd sort of like to get you on the same page where you're -- we're talking about people, we're talking about terms. And I'll make a decision.

MR. GRAHAM: Okay.

MS. MELVIN: Yes, Your Honor, I would propose that it sounds now as though -- and plaintiff's counsel can correct me if this is wrong, but 5 (F), they're no longer seeking that provision, which is the plaintiff's provision that confidential information should be given to officers, directors and other employees or agents of a party. So my understanding is they're no longer seeking that. Plaintiff's counsel can correct me if that is mistaken.

So that we've just left to the issue of Mr. Thallemer and Mr. Reddy. So we would propose giving plaintiffs, perhaps, two weeks to submit a declaration on behalf of those individuals, and then providing two weeks for plaintiff -- for defendants to respond --

THE COURT: Yeah.

MS. MELVIN: -- if that's reasonable with the Court and acceptable to plaintiffs.

THE COURT: So we're talking about two individuals, let's be clear. And I'd like to -- or would -- how do you feel, assuming that access is allowed, that there be a two-year patent prosecution bar?

MR. GRAHAM: Your Honor, that's not a problem at all with us, because these individuals were not involved in this particular technology prosecutionwise.

THE COURT: How about defendants? How about two years?

MS. MELVIN: I think that would be acceptable, Your Honor.

THE COURT: Okay. Good. We're making some progress. And I think your two-week schedule's good. But I'd like someone to put it in a letter or I can so order or in an order, for you to respond, so that we have -- we have that all going, which would be very helpful.

Now, another issue was raised with -- excuse me for a second. I want to just go off the record and I'll talk to.

(Pause in proceedings)

THE COURT: Yeah, I mean, my career clerk, Mr. Conlon, who has tremendous experience in this area too, just wonders whether we can really just have a deal. In other words, would defendants be agreeable to the -- based on the assertion that they have nothing to do with patent prosecution or anything like that, would you be -- and since it's not going beyond that, we have two individuals in two years, can we have a deal without having papers?

MS. MELVIN: Your Honor, this is Emily Melvin for Roxane. We do have an additional concern, which we have

raised in the letters, and I'm happy to go into more detail, if Your Honor would like, but that is that we now have two instances of what we view as the improper disclosure of Roxane's confidential information: one to Mr. Thallemer, which Mr. Thallemer submitted a declaration last night. I was on the call that was at issue. And I disagree with the version of events that was set forward. I'm happy to discuss that more, if Your Honor would like.

And the second instance is that there is a Ms. Golaris [phonetic], who is apparently outside counsel but is not admitted pro hac vice, and we learned just within the last few days that she did receive some of Roxane's confidential information, even though she has not be admitted.

So we do have some concerns with respect to Mr. Thallemer in light of the declaration and the fact that it doesn't accurately reflect the events of the call. So we would like some time to further consider that. And I do think the briefing schedule would be appropriate in that regard.

THE COURT: All right. I mean, that's fine. I mean, that would -- yeah.

You're saying this third person? I didn't really follow that. This woman?

MS. MELVIN: Yes. So, Your Honor, I believe -- my

understanding is that she is outside counsel for plaintiffs, but she was not admitted pro hac vice, and we were not aware that she was receiving our confidential information in any way. And we just learned within the last few days that she has, in fact, been given our confidential information. We understood last night that plaintiffs were intending to seek her admission pro hac vice, but now we understand that may not be the case.

So it is -- it is a concern. We think that, you know, before confidential information is given to any counsel or any person, we need to go through the steps of admission pro hac vice or otherwise, the other appropriate steps under whatever DCO we agree on.

THE COURT: Well, I have no problem with that. That would be the terms and the viol- -- you know, an issue of the DCO. I just was trying to get down to make it a deal, you know, to see that we could do that. And -- I mean, because I guess you're claiming that there's been violation of -- at this point. Is that what you're saying?

MS. MELVIN: Yes, Your Honor, that is our contention. And we have been attempting to speak with plaintiffs about this for the last several months. And frankly we are concerned about Mr. Thallemer's access to information in light of the fact that Wolf [phonetic], the other attorney for Roxane and I, who were on the call,

disagree with his statement of the events that took place. And, in fact, some of the facts in the declaration that we allegedly revealed are not even accurate about Roxane. So it's clearly not accurate of what was said on the call.

THE COURT: No, I hear you. And I don't know if that -- and I'm not -- I'm not cutting you off. I haven't read it. I don't know. It seems to me a different issue. I'd like you to strongly consider whether we can agree without too much further argument -- I'm not forcing you to. You can certainly have more time, and we can put the order -- you know, the sort of, quote, briefing order in place.

But what you've said doesn't seem to change the fact that -- I mean, they have a sort of restrictive position -- I mean, nonrestrictive or a limited position of two people and two years that they've represented have nothing to do with patent prosecution or competitive -- or this product area, shall we say.

So I would like to see if that could be worked out as a deal. I think that would be a good one.

MS. MELVIN: Well, I think, Your Honor, in order to -- before we're able to reach a deal, I think we would like some sort of declaration from Mr. Thallemer and Mr. Reddy detailing exactly what their positions are so that we can further consider it, because at this point, we've had heard that they're not involved in patent prosecution, but

there is -- there are other competitive decision-making issues that could be involved as well.

So it very well may be that plaintiffs provide the declarations and then we withdraw our objections. But I think we need to see those declarations first.

THE COURT: Fair enough. I mean, then that's what we'll do.

Now, I know that the letter submitted last night really didn't go to the issue that we're -- you know, to the DCO. But it's about -- there's mention of samples and vil- -- I mean, I thought I had said at one point, you should get the samples. No?

MS. MELVIN: Your Honor, we -- from Roxane's position, we've informed plaintiffs that we are working with our client to figure out how much they have and how much we're able to give them. They've requested an extremely -- what from our view is an extremely large amount, so we're -- in our view, we're still working that out. We're working with the client.

THE COURT: Okay.

MS. MELVIN: We don't think it's ripe for the Court's intervention.

THE COURT: You feel differently, Mr. Graham?

MR. GRAHAM: Oh, quite differently, Your Honor. But, again, we consulted with our expert. We don't -- tests

are expensive. Our client doesn't want to do any more tests than it has to. So we have no motive or incentive to try to get more material than we need -- than our clients need to test this material to find out, you know, a number of things about it and to do it in the right way so that we are assured that it's -- accurately represents the material. You know, we consulted with our expert about that, and we've done quite a bit of work actually to determine the appropriate amount: 30 grams, which is about an ounce, from each of these reserve samples that the FDA requires be maintained.

There's a lot of detail in that, Your Honor. I don't know if you want to get into all of that.

THE COURT: No. And I'm not prepared to. I understand the issue. But I think you should continue to work it out. I mean, we've got to get there.

MR. GRAHAM: We're trying.

THE COURT: You're entitled to samples, as far as I'm concerned.

I understand the other side. You know, sometimes there's a limited number left or that can be found that would be appropriate and I -- but you need to talk to one another and work it out and move it along, because the cases are going to start getting old. And you're going to have a lot of, you know, battles. I can see it already.

MS. MELVIN: Yes, Your Honor. We're prepared for

that.

MS. VYAKARNAM: Your Honor.

THE COURT: Go ahead. Okay.

MS. VYAKARNAM: For Amneal, we've already offered them samples.

THE COURT: Oh, good.

MS. VYAKARNAM: But the issue is just the quantities.

THE COURT: The quantity.

MS. VYAKARNAM: We also -- the quantity they asked of 30 grams is large. And we've offered to give them 5 grams, and we've talked to our experts, and we think that's a fair amount, and they should be able to do the testing needed, you know, more than a couple of times with that amount, but, you know, we're just waiting for them to agree to that amount, and we're ready to ship our samples to them.

THE COURT: But let me just ask you -- and I don't understand enough about the strategy on something like this. I mean, okay, I hear what you say. And maybe -- you know, I think frankly, Plaintiff, you should consult with your expert and request the minimum amount that an effective testing can be done.

But I'm now going back to Amneal, is your offer of 5 grams, is there some strategy to that? Or you simply don't have it or it's -- I mean, what's the reason? Why not just

go along with -- I mean, is there ...

MS. VYAKARNAM: One of the things that plaintiffs referred to as saved for the FDA purposes are exactly that. They're saved for the FDA purposes. We can't really take that, a big chunk of that amount, reuse it for litigation. So of course, they're limited in the quantities.

And from my experience in other cases, 5 grams is already more than what we typically give for these kind of testing. So it's more than sufficient amount.

And plaintiffs have requested samples of each and every lot --

THE COURT: Yeah.

MS. VYAKARNAM: -- which is a lot too. I mean, they haven't given us a good reason for why they need each and every lot. And they haven't even told us if they're going to test each and every lot. We want to know if their position is going to be they need to test every lot to prove an infringement in each lot.

THE COURT: Yeah. Yeah.

MR. GRAHAM: Your Honor, if I could speak to that and just repeat what I had mentioned before. Our clients have no desire or incentive to want to test any more material than absolutely necessary. They have no reason to want more than they need.

One thing that would help this quite a bit, I

believe, is if we could get information from the defendants as to how much they have. And, you know, we'll receive that confidentially or whatever. But, you know, we're shooting in the dark here, because we asked for 30 grams. We understand that conventional in the industry is 500 grams, which is a little -- about a pound and a half or a little more than a pound from each big, large batch of pharmaceuticals. That is conventional. That's what people use as their amount for retained samples.

So we think that 30 grams is what we need to do the test. We don't think that's inordinate percentage of the total.

But, again, we don't know how much they have, and they won't give it to us, because they say it's not necessary. We tried to explain our reason for wanting to know how much they have because they say it's too much of what we -- our client has, but how do we know that? We don't know how much their clients have, and they won't tell us.

So we're doing our best, Your Honor, to try to reach on agreement on these amounts.

THE COURT: Well, I'd like you to meet and confer. I think you should be able to work this one out. I'm sorry if you can't. I don't know what I would do. I'd get affidavits from the experts on both sides and --

MR. GRAHAM: Yes, sir.

THE COURT: I mean, I don't know what else. You know, I'd have to make some kind of a call. Probably wouldn't be the most informed call, but ...

MS. VYAKARNAM: Your Honor, our position is that they're not entitled to discovery on how much we have from each and every lot that we've ever --

THE COURT: You may be right on that. I don't see that as being relevant. I mean, it might be helpful, because I'm curious to the decision, but I agree with you, that that's not really discovery that is relevant to the issue.

But I'm trying to help you -- to sort of come to an agreement on this. If you want me to make a call on it, I'll make a call on it. You'll give me expert certifications and do the best I can.

I mean -- and with that, I may want to know how much you have, as a matter of fact; perhaps even for *in camera*. But I mean, you know -- although -- I mean, if that's a really serious concern, we do the best we can. But I mean, if plaintiff's expert is saying, that's the minimum they need to test, I don't know, how do you decide that? How would you decide something like that? I mean, I'm not trained in science. I can hear from both sides. A credibility decision? I don't know what to do. I don't mean I don't know what to do. That's what I would have to do is make the best decision, if you can't do it.

But I really at this point I want you to kind get together and start cooperating a little, not that you haven't been, but I'd like to see the samples, meet and confer on that, follow up on it. We'll get the affidavits. I'm hoping for a potential deal on the discovery confidentiality order.

I think we need a proposed new scheduling order. I'd like you to confer on that. And if it's something that you have disputes on, I will, you know -- what? You know, I think that's something that we need. Like there was a dispute about something in December, on December 12th, I think, it was. I think -- but that's past. I mean, is that what you're talking about?

MR. POULLAOS: That's right, Your Honor, I can talk to that, if you --

THE COURT: Is that still a dispute? Or are we past that?

MR. POULLAOS: Well, in the sense that the schedule Your Honor just entered has a December 9th date that passed, we weren't able to provide our evidence opposing their proposed claim constructions, the plaintiff's proposed claim constructions, because we didn't have their constructions. So it was impossible for us to meet that date, which is why we, you know, short of asking that plaintiffs have waived their claim construction positions, what we did is we submitted a letter asking for those dates in December to be

advanced, because plaintiffs had not given us their constructions.

And so that's where we are right now.

THE COURT: But where are you right now? I mean, is it on consent, or is there a dispute?

MR. POULLAOS: Right now, it was on consent. And actually today is the day that the parties had agreed to exchange opposing evidence. We're ready to do so. I don't know if plaintiffs are. If you want to push that out a couple of days as well, that's -- we can talk about that.

But what our schedule does is provide for that disclosure to take place today, and then the other deadlines on the Markman schedule were kicked out a week. Everything else remains the same.

THE COURT: So I mean, this proposed sixth amended scheduling order is -- we have it. I mean, should I enter that? Is that what --

MR. POULLAOS: Unless you need to -- more extensions. I don't know.

MR. GRAHAM: Yeah, because I -- we've had a misunderstanding about that, because we thought we were already operating under the fifth -- we had filed a letter saying we agreed with that. And so I thought we were under the new dates. I wasn't under the impression that anything was due today in regard to --

MR. POULLAOS: That's one of the new dates. Your Honor, this is -- honestly, this is one of the problems that's been happening.

THE COURT: I know, but I want to get an operative scheduling order and then live by it, if I can.

MR. POULLAOS: All right.

THE COURT: Okay? But there seems to be a misunderstanding here.

MR. POULLAOS: I think the only misunderstanding right now is on that December 16th date, the date today for exchange of evidence. So if you want to agree on a Tuesday or --

MR. GRAHAM: That's fine. That's fine.

MR. POULLAOS: -- whatever it is.

MR. GRAHAM: Tuesday's fine.

THE COURT: Tuesday.

MR. POULLAOS: So that December 16th date would be December 21st, and that's in the sixth amended. So --

THE COURT: But I mean, you're referring to the fifth consent -- the amended scheduling order. Right? There's --

MR. GRAHAM: We had actually indicated we agreed with the sixth --

THE COURT: The sixth, you agree. So everyone agrees. It's on consent.

MR. POULLAOS: With one proviso, paragraph 5, December 16th will be December 21st.

THE COURT: Okay. We'll deal with that.

Is there anything else I can deal with right now? Okay. Anything else right now, counsel?

MR. GRAHAM: I want to apologize, Your Honor, for my tardiness.

THE COURT: No, I understand. Traveling's tough at this time. It's okay with me. It's to your colleagues, and I'm sure they'll accept your apology.

MR. GRAHAM: And I want to apologize for November. I had pneumonia twice.

THE COURT: I'm sorry to hear that. Yeah, I'm very sorry.

MR. GRAHAM: So it was kind of difficult to keep up with things. But hopefully with better communication, we can move this forward, because we certainly have -- we're being encouraged by our client to move it forward.

THE COURT: I'm sure you are. Well, I wish you good health and all good health and happy holidays. And be in touch with me if there's a problem. I'm going to try to, you know, be active on the case. Okay?

UNIDENTIFIED SPEAKERS: Thank Your Honor.

THE COURT: Is there something else? They're going to submit that to me. Oh, you mean the dates? Yeah, I

want -- I mean, you're going to submit the dates for this affidavit business. Right?

MR. POULLAOS: We're going to submit a letter outlining the schedule.

THE COURT: Soon. Right?

MR. POULLAOS: Yes.

THE COURT: Real soon. I mean the letter. You know, I don't know about the dates, because we're going to reach a deal. Take care.

(Conclusion of proceedings at 1:01 P.M.)

Certification

I, SARA L. KERN, Transcriptionist, do hereby certify that the 36 pages contained herein constitute a full, true, and accurate transcript from the official electronic recording of the proceedings had in the above-entitled matter; that research was performed on the spelling of proper names and utilizing the information provided, but that in many cases the spellings were educated guesses; that the transcript was prepared by me or under my direction and was done to the best of my skill and ability.

I further certify that I am in no way related to any of the parties hereto nor am I in any way interested in the outcome hereof.

S/ ***Sara L. Kern*** 11th of January, 2017

Signature of Approved Transcriber Date

Sara L. Kern, CET**D-338
King Transcription Services
3 South Corporate Drive, Suite 203
Riverdale, NJ 07457
(973) 237-6080